UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* BERNARD LISITZA, *et al.*	)	
Plaintiffs,	)	
v.	)	No. 06 CV 6131
	)	Chief Judge Gottschall
PAR PHARMACEUTICAL COMPANIES, INC., *et al.*,	)	
Defendants.	)	

COMPLAINT OF THE STATE OF MICHIGAN

The Attorney General of the State of Michigan, Bill Schuette, on behalf of the State of Michigan, and through Elizabeth Valentine, Assistant Attorney General, alleges the following:

I. INTRODUCTION

1. Plaintiff Bernard Lisitza ("Relator") filed this action in 2006 against several Defendants, including Par Pharmaceutical Companies, Inc., alleging violations of the Michigan Medicaid False Claim Act, MCL 400.601 *et seq.*

2. The Michigan Attorney General has elected to intervene in the action filed by Relator to proceed with civil claims against Defendant Par Pharmaceutical Companies, Inc. (Par).

3. The State of Michigan, through Relator Bernard Lisitza, seeks to recover treble damages and other relief under the Michigan Medicaid False Claim Act, MCL 400.601 *et seq.*, and to recover damages, restitution, and other monetary relief under the common law theory of unjust enrichment.

4. The State of Michigan alleges that Defendant Par violated the Michigan Medicaid False Claim Act, by knowingly causing submission of false claims to the State of Michigan for excessive reimbursement of prescription drugs prescribed for Medicaid beneficiaries.

5. Defendant Par develops, markets, and sells generic drugs. As detailed in this Complaint, Par increased its sale of certain generic drugs through an illegal scheme to fill prescriptions with higher-priced products rather than supplying the drug in the form and strength prescribed by the Medicaid beneficiary's physician. Defendant's scheme was designed to result in excessive Medicaid reimbursement by evading government price limits on generic drugs.

6. The alleged conduct complained of in this suit occurred during the time period 2001 through at least mid-2006.

II. JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1345, 1367(a), and under §§ 31 U.S.C. 3730(a) and 31 U.S.C. 3732(b). The Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a), because Defendant transacts business in the Northern District of Illinois. The Court has jurisdiction over the State claims pursuant to 28 U.S.C. § 1367(a).

8. Venue is proper in the Northern District of Illinois, Eastern Division pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) and because Defendant committed acts in violation of 31 U.S.C. §§ 3729-33 within the District.

III. PARTIES

9. Plaintiff State of Michigan brings this action on behalf of the Michigan Medicaid program administered by the Medical Services Administration, Michigan Department of Community Health (MDCH) and on behalf of the interest of the People of the State of Michigan

in this cause. Michigan brings this action pursuant to the Michigan Medicaid False Claim Act, MCL 400.601 *et seq*. and the common law and statutory authority of the Attorney General to represent the State of Michigan.

10. Relator Bernard Lisitza is a citizen and resident of the State of Illinois. He brings this action on his own behalf and on behalf of the State of Michigan pursuant to MCL 400.610a of the Michigan Medicaid False Claim Act.

11. Defendant Par Pharmaceutical Companies, Inc. (Par) is a Delaware corporation with its principal place of business in New Jersey.

IV. MICHIGAN'S MEDICAID PROGRAM

12. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

13. The federal involvement in Medicaid is largely limited to providing matching funds and ensuring that states comply with minimum standards in the administration of the program.

14. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation (FFP). 42 U.S.C. §§ 1396 *et seq*.

V. MEDICAID GENERIC DRUG PRICING

15. Each state's Medicaid program covers outpatient drugs prescribed by a physician. 42 U.S.C. § 1396r-8(k)(2). Typically, this includes only drugs approved for safety and effectiveness as prescription drugs under the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*.

16. Reimbursement for drugs prescribed for Medicaid patients are priced according to specific dosage forms and strengths, as required by federal and state statutes and regulations. The federal statute governing Medicaid's payment for covered outpatient drugs recognizes that drugs will be priced according to specific dosage forms and strengths. 42 U.S.C. § 1396r-8(b)(2)(A), (c)(1)(A), (c)(2)(A), (g)(2)A)(I)(bb), and (k)(7)(C)(i).

17. Under federal and state law, each dosage form or strength is a different drug, even if each drug contains the identical active ingredient. For example, a Zantac 150 mg *tablet* is a different drug than a Zantac 150 mg *capsule*. Different dosage forms and strengths vary in potential effectiveness and safety concerns that are significant to physicians, patients, and the FDA.

18. The FDA requires each specific dosage form and strength to gain approval as a new and unique drug, regardless of whether the drug's active ingredient was approved in a different dosage form or strength.

19. The United States Pharmacopeia (USP) is a primary resource for defining and listing approved drugs under federal and state law. The USP establishes that different dosage forms and strengths with the same active ingredient are different drugs under federal and state law.

20. FDA concluded that patients and healthcare practitioners have a significant interest in, and legitimate concerns regarding the *form* of oral drug products, and that tablets and capsules, while similar in many respects, have special properties that may make one or the other more advantageous in the treatment of certain patients. Tablets and capsules, therefore, should not be regarded as the same dosage form. *Id.* (emphasis in original).

21. State law requires pharmacies to provide the patient with the drug that the doctor prescribed. Pharmacies may not dispense a capsule when the doctor prescribed a tablet, or a tablet when the doctor prescribed a capsule.

22. Michigan law allows a pharmacist to substitute a generic drug for a therapeutically equivalent brand name drug -but only if the generic drug is equivalent and less expensive. MCL 333.17755.

23. Michigan adopts FDAs determination of whether drugs are therapeutically equivalent, also known as "AB rated." The FDA has established that drugs with different dosage forms or strengths are not therapeutically equivalent or "AB rated," even if they have the identical active ingredient.

24. The federal Medicaid law governing pricing for covered outpatient drugs also incorporates FDA determinations of therapeutic equivalence in setting price limits for generic drugs. 42 U.S.C. § 1396r-8(k)(7)(c)(I).

25. One of the ways the Medicaid program contains healthcare costs is by setting a price ceiling on certain generic drugs. For popular generic drugs that are widely prescribed and supplied by multiple manufacturers, federal and state governments set maximum prices that they will pay for a drug. 42 U.S.C. § 1396r-8(e)(4).

26. By law, popular generic drugs are subject to a Federal Upper Limit (FUL). FULs are set by the Centers for Medicare & Medicaid Services (CMS) when: 1) at least three versions of the drug are rated therapeutically equivalent by the FDA, and 2) the drug has at least three suppliers (listed in national compendia). 42 U.S.C. § 1396r-8.

27. The federal Medicaid law governing pricing and manufacturer rebates for covered outpatient drugs also incorporates FDA determinations of therapeutic equivalence in setting price limits and rebates for generic drugs. 42 U.S.C. § 1396r-8(k)(7)(C)(i).

28. States must not exceed the federal upper price limits, but can set lower prices. Michigan sets its own generic drug reimbursement ceiling, setting a maximum allowable cost (MAC) for most generic drugs. Popular or frequently prescribed generic drugs tend to have a lower price.

29. FULs apply only to specific dosage forms and strengths, as each is a distinct drug. For example, CMS Transmittal 37 which was circulated on November 20, 2001, established a FUL of 34 cents for ranitidine 150mg tablets, but no FUL was set for ranitidine 150mg capsules. Exhibit 3 at page 18.[1]

30. Medicaid pays different prices for different dosage forms and strengths. The disparity in reimbursement can be striking. A capsule may cost many times more than a tablet, even though the drugs may have the same active ingredient. For example, ranitidine (a commonly prescribed drug that inhibits production of stomach acid) in capsule form may cost the government four times more than a tablet, even though the active ingredient and dosage strength is the same.

VI. DEFENDANT KNOWINGLY CAUSED THE PRESENTATION OF FALSE CLAIMS

31. Par markets and sells generic prescription drugs. The generic drug industry is highly regulated. Par knew the laws applicable to prescriptions and reimbursement by government programs for generic drugs.

[1] Exhibit numbers correspond to the exhibits attached to relator's amended complaint and the federal complaint.

32. Starting in April 1999 through December 31, 2006, Par increased its sales of generic drugs by contriving an illegal switching scheme to fill Medicaid and other government health insurance program prescriptions with Par's higher-priced products rather than the specific drug that the patient's doctor had prescribed. The scheme was specifically designed to evade price limits on generic drugs and was touted as a means for its customers - pharmacies and wholesalers - to increase their profits by evading price limits on specific drugs.

33. Par used its industry expertise to anticipate and capitalize on price disparities that occurred when government price limits were placed on the generic form of particular popular and widely used drugs. Par deliberately marketed generic drugs with the same active ingredient as the popular brand name drugs, but changed the dosage form or strength to avoid a MAC or FUL price limitation. Par conspired with, enabled, and aided Walgreens, Omnicare, and other pharmacy providers to make false and fraudulent claims and statements to obtain reimbursement for the higher priced drugs, knowing this caused evasion of federal and state price limitations and required switching the prescribed drugs from the form and strength prescribed by the physician. Par encouraged the unlawful switching of prescriptions from the physician-prescribed drug to drugs of a different form or strength to increase profitability.

Ranitidine Tablets to Capsules

34. Ranitidine is the generic form of the brand name drug Zantac, used to treat heartburn, ulcers, and other stomach acid conditions. Doses of 150 and 300 mg of ranitidine require a prescription. During the time period at issue, brand-name Zantac and generic ranitidine were prescribed almost exclusively in tablet form.

35. Par implemented a fraudulent scheme to evade Medicaid reimbursement limits for tablets of ranitidine, the generic form of the brand-name antacid Zantac. The scheme caused

Walgreens and other pharmacies to fill prescriptions for Zantac and generic ranitidine tablets with Par's capsule form of the drug, to achieve huge profits from making the switch.

36. Par knew ranitidine tablets would soon be subject to Medicaid price limits because on April 6, 2000, the federal Centers for Medicare and Medicaid Services (CMS) announced that it was setting a Federal Upper Limit for ranitidine tablets. Par saw the opportunity to profit by evading this limit through marketing a scheme to fill ranitidine *tablet* prescriptions with Par's ranitidine *capsules*.

37. After the CMS announcement, Par persuaded Walgreens and other pharmacies to fill all Zantac and ranitidine prescriptions with Par's ranitidine capsules. Par made presentations, distributed flyers, and used other marketing techniques to convince pharmacies to participate in the switching scheme to evade the upcoming Medicaid price limits. These activities caused the submission of false claims for higher priced, illegally switched, drugs.

38. Par's marketing presentation to Walgreens, prepared in November 2000 by Par's executive vice-president of sales and marketing, Nick DiMaio, explained how Walgreens could make more than $75 million in additional profits by filling prescriptions for Zantac and ranitidine tablets with Par's ranitidine capsules, even though Par's capsules would cost Walgreens considerably more than the competing tablets.

39. Par's "Walgreens Ranitidine Analysis" shows that Par was going to charge Walgreens five times more for its ranitidine capsules than competitors were charging for ranitidine tablets. Walgreens' acquisition cost would be 9.5 cents for each Par capsule but only 1.9 cents for a competitor's tablet, for a per-prescription acquisition cost (per 60 count) of $5.70 for Par's capsule versus only $1.14 for a tablet. Exhibit 5.

40. As part of its Walgreens Ranitidine Analysis, Par highlighted the upcoming Medicaid price limits for ranitidine tablets, known as the "Proposed HCFA MAC." HCFA was the acronym for the federal Health Care Finance Administration of the Department of Health and Human Services (now known as the Centers for Medicare and Medicaid Services or CMS). The MAC is the Maximum Allowable Cost, a Medicaid price limit set for generic drugs reimbursed by state Medicaid programs, including Michigan's Medicaid program.

41. Par explained to Walgreens that while Par's capsules cost more, there would be no Medicaid MAC price reimbursement limit for Par's capsules. Medicaid would pay Walgreens $71.45 per prescription for Par's capsules, but only $5.35 for a prescription filled with tablets.

42. Par's analysis showed that by evading the MAC on ranitidine tablets, Walgreens could make a profit of $65.75 for each Par capsule prescription. This compared to a profit of only $4.21 for each tablet prescription - 15 times more profit, even while paying Par five times as much for the capsules.

43. Par's Walgreens Ranitidine Analysis was detailed. It calculated that Walgreens filled 1,222,917 ranitidine prescriptions annually. Applying simple math, Par projected that Walgreens would make $80,400,656 in profits by instituting the tablet-to-capsule switching scheme, but only $5,143,588 if the company dispensing the prescribed tablets. Exhibit 5.

44. Nick DiMaio, Par's top marketing executive, often assisted at these presentations by Julie Trendowicz, Par's Vice President of Sales and Marketing. In an interview with the FBI, Trendowicz confirmed Par's marketing plan for evading Medicaid price limits:

> Q. Well, when you go in and offer the product, you market it on the basis of there being a MAC on the competition, as opposed to the product that Par wishes to sell, don't you?

A. If we offer that program to [Walgreens], yes, that's what we would have.

Exhibit 6 at Day 2, pp 456-457, lines 20-6.

45. On, May 15, 2001, Bill Groth, Walgreens' divisional manager for pharmacy purchasing, wrote an email regarding ranitidine stating:

> [S]ince these items are highly competitive 3rd party payors and the government have created MAC (maximum allowable cost) pricing which limits our reimbursement . . . By switching to a capsule dosage form we have discovered that there are not currently constraints on MAC . . . At a 50% conversion rate increased GP [gross profit] dollars could achieve approximately $1.66MM per month . . .

Exhibit 7.

46. Groth later testified about this email and specifically how he came to know about the lack of a MAC on Par's ranitidine capsules:

> Q. Further down in the email, you wrote: "Since these items are highly competitive, third-party payers and governments have created MAC's which limits our reimbursement." And then you stated that by switching to the capsule, you've discovered there are no constraints on the MAC. How did you discover that there were no constraints on the MAC?
>
> A. I believe that, again, was presented by Par Pharmaceutical.

Exhibit 8 at p 34, lines 5-15.

47. Walgreens agreed to buy Par's ranitidine capsules for the purpose of engaging in the switching scheme. In a company-wide email sent on July 12, 2001, Tom Lawlor announced the switching program:

> On Tuesday, July 16, 2001, we will begin automatically switching all prescriptions for ranitidine 150 mg and 300 mg tablets (Mylan) to ranitidine 150 mg and 300 mg capsules by Par Labs. Brand name prescriptions for Zantac tablets will also be converted to the new dosage form when the respective generic is dispensed.

Exhibit 9.

48. By July 2001, Walgreens had configured its Intercom Plus pharmacy computer system so that all prescriptions for Zantac or generic ranitidine were automatically filled with Par's ranitidine capsules.

49. In furtherance of the Par-initiated scheme, Walgreens required its pharmacy employees to fill all Zantac or ranitidine prescriptions (including refills) with Par's capsules regardless of what had been prescribed and in violation of federal and state law and regulations.

50. To facilitate the ranitidine switching scheme, Walgreens and Par created a health resources partnership. As part of this partnership, Par marketed ranitidine capsules as if they were therapeutically equivalent to, and thus legally interchangeable with, ranitidine tablets, when in fact they were not. Exhibit 11.

51. Drugs that are therapeutically equivalent and interchangeable are known as AB rated products. Par used various means to convince pharmacists that Par's ranitidine capsules were therapeutically equivalent and AB rated to ranitidine or Zantac tablets, when they were not.

52. As Par intended, Walgreens used this information to market Par's ranitidine capsules. Tom Lawlor, Walgreens' director of pharmacy marketing, conveyed Par's misleading information to Walgreens pharmacists - that "ranitidine capsules by Par are AB rated generic products." He told pharmacists that "[the conversion program] will provide a unique opportunity to have meaningful conversation with your patients and assure them their medication is exactly the same and that the only change is to a capsule dosage form." Exhibit 9.

53. In July 2001, Lawlor's false assertions about the equivalency of Par's capsules to tablets came to the attention of the Illinois Department of Public Health. On July 25, 2001, IDPH issued a written rebuke to Walgreens, concluding that:

> Your communication to Walgreen pharmacists indicated that the *ranitidine* 150 mg *and* 300 mg *capsules* intended to be dispensed by Walgreen pharmacists were "AB rated generic products." Please note that the Par ranitidine 150 mg and 300 mg capsules are only rated equivalent to other manufacturers' ranitidine capsules listed in the current edition of the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations . . .*"
>
> To infer that Par ranitidine capsules are "AB rated generic products" with any manufacturer's ranitidine tablets is false and deceptive. (Emphasis in original)

Exhibit 12.

54. After Walgreens learned it was under federal investigation for the illegal switching scheme, it decided to reverse the ranitidine switching practice. On August 24, 2004, Bill Groth, Walgreens' divisional manager for pharmacy purchasing, sent an email to George Riedl, Walgreens' senior vice-president of the drug store marketing division:

> FYI . . . John Ziebell and myself, along with Tom Lawlor had a second meeting with [Walgreens in-house counsel] Bryan Schneider in regard to questions and concerns from government agencies on ranitidine and fluoxetine dosage form conversions. These agencies suggest we are actively switching dosage forms and thus the states are paying higher reimbursement which they view as overcharges to the public. Additionally, they suggest our pharmacists are not calling for physician approval. Today's meeting was as a result of discussions Bryan has had with others within our company and outside counsel and ultimately that groups [sic] recommendation to adjust our policy.

Exhibit 13 at 05218-19.

55. As a result of this meeting, beginning in September 2004, Walgreens began to fill customers' new ranitidine prescriptions with ranitidine tablets instead of Par's capsules.

56. On November 17, 2004, Lawlor explained in an email:

> On the advice of in-house and outside counsel due to 3 state attorneys general and the US AG suing us - we were advised to quietly convert to the same dosage forms. There is an estimated $5 million hit to the company per year in GP. This decision did not come easily or lightly and was made in FY 2005 - not '04.

Exhibit 14 at 09542.

57. Walgreens approached Par for a future price reduction on several drugs, including ranitidine, so it could recoup lost profits because of the cost incurred by switching back to tablets.

58. In a September 21, 2004 email, Frank DeStefano, Walgreens' general merchandise manager, explained:

> FYI . . . As discussed in the Divisional Review, the impact of the tab-to-tab and cap-to-cap cross reference on ranitidine and fluoxetine is estimated at a gross profit loss of about $9.94 M for FY 2005. In anticipation of this and in order to defray the loss, John Ziebell has gone to Par and Teva to obtain lower costs on both capsules AND tablets for both entities.

Exhibit 15 at 05260.

59. To get the price reduction, Walgreens contacted Julie Trendowicz, Par's Vice President of Sales and Marketing, who had responsibility for the Walgreens account and who had participated in the switching pitch made to Walgreens earlier. Trendowicz agreed to the price reductions referenced in DeStefano's email.

60. Getting this price reduction had a significant impact on Walgreens' profit losses. As DeStefano explained in an email to John Ziebell and Heather Zenk:

> Your work on getting price reductions on fluoxetine and ranitidine in response to the 8/27 change in the cross reference on Intercom Plus helped us recover approximately $2.2M annually (defrayed the estimated annual profit loss of $9.94M down to $6.73M) for the company. OUTSTANDING JOB . . . THANK YOU!!!!

Exhibit 15 at 11048.

61. Par not only conspired with Walgreens to implement the illegal switches, but it also paid millions to reverse the financial consequences after Walgreens decided to stop the practice.

62. Par knew that Walgreens continued to refill prescriptions with capsules for current customers in 2004.

Fluoxetine Capsules to Tablets

63. Par also implemented a fraudulent scheme to evade Medicaid reimbursement limits for fluoxetine capsules, the generic form of the brand-name anti-depressant Prozac. Doses of 10 and 20 mg required a prescription and were covered by Medicaid. Par caused Walgreens and other pharmacies to fill prescriptions for Prozac and fluoxetine *capsules* with Par's *tablets*. Par convinced its customers to buy tablets by promoting the huge profits to be made by participating in this illegal drug switching scheme.

64. During the relevant time period, both brand-name Prozac and generic fluoxetine were prescribed almost exclusively in *capsule* form. In its 20 mg strength, Prozac was only available as capsules. Prior to Prozac losing its patent protection on August 1, 2001, all prescriptions for Prozac 20 mg could only be filled with capsules. Prescriptions for Prozac 10 mg were typically filled with capsules as well.

65. Eli Lilly, the manufacturer of Prozac, made a 10 mg tablet, but never marketed a 20 mg tablet.

66. With the expiration of Eli Lilly's Prozac patent looming, numerous generic manufacturers submitted applications to the FDA in order to sell fluoxetine tablets.

67. Alphapharm and Genpharm, originally named as defendants in this action, began to develop fluoxetine 10 and 20 mg tablets, and gave Par the exclusive sales and distribution rights in the United States.

68. Par developed a marketing campaign for fluoxetine tablets, targeting patients, doctors, pharmacists and pharmacies.

69. Walgreens' Bill Groth, divisional manager for pharmacy purchasing, confirmed that Par proposed the fluoxetine capsule-to-tablet switch:

> Par presented . . . that they were coming out with a [fluoxetine] tablet and would we be interested in making that conversion from a [Prozac] capsule in this case back to a tablet on the fluoxetine tablets.

Exhibit 8 at p. 40-41.

70. Par claimed that fluoxetine tablets were easier to swallow than capsules despite its own contrary marketing for ranitidine, where it emphasized that capsules were easier to swallow. For example, in advertisements and in a presentation to pharmacy customers for fluoxetine tablets, Par claimed that "[Fluoxetine's] small size makes tablets easier to swallow" and that "patients prefer tablets over capsules when they have a preference between the two dosage forms." Exhibit 21. At the same time, when promoting ranitidine capsules, Par claimed that capsules were "easier to swallow." Exhibit 11 at 00068.

71. In sworn testimony, Par Vice President Trendowicz confirmed that fluoxetine tablets were marketed by comparing "a Par product that was not subject to a MAC versus a comparison of a non-Par product that was subject to a MAC." Exhibit 6 at Day 1, p. 128, lines 13-20.

72. In December 2002 a federal upper limit price of $0.58 was established for fluoxetine 10 mg capsules and $0.60 for 20 mg capsules. Exhibit 23. States, including Michigan, also established maximum allowable cost (MAC) prices for fluoxetine capsules that were at or below the FUL as required by federal law and in compliance with federal regulations.

73. Before the patent on fluoxetine capsules expired, Par knew there would be competition in the market which would lead to the imposition of federal and state maximum prices. But Par knew that there would be little or no competition in the fluoxetine *tablet* market,

so price limits on tablets were unlikely.

74. Walgreens, Omnicare, and the rest of Par's customers who participated in the scheme reaped the anticipated benefits of the illegal switching.

75. For example, during January 2003, the Indiana Medicaid program paid $0.69 per 20 mg fluoxetine capsule, while it paid $1.91 for Par's fluoxetine 20 mg tablet.

76. Par paid wholesalers and distributors with free products or other incentives to engage in a fluoxetine telemarketing program to pharmacies on Par's behalf. Par gave the wholesalers scripts to use when making phone calls to customers. These scripts contained Par's key selling point: Medicaid reimbursement on its fluoxetine tablets allowed pharmacies to make huge profits at the government's expense.

77. On October 16, 2001, Nick DiMaio, Par's executive vice president of sales and marketing, sent one of these telemarketing scripts to Amerisource, a drug wholesaler, which stated:

> Many third party plans and state agencies are issuing MACs or upper limits on reimbursement on fluoxetine. Par's 20 mg fluoxetine tablets are priced to allow you to continue to make acceptable profits when filling prescriptions for fluoxetine 20 mg.

Exhibit 24.

78. Par knew that pharmacists were the key to a successful fluoxetine switching program. Because pharmacists are licensed by states, Par had to convince pharmacies like Walgreens and Omnicare that their pharmacists would be willing to switch a fluoxetine tablet for a fluoxetine or Prozac capsule. Exhibit 27.

79. In furtherance of this goal, Nick DiMaio, Par's executive vice president of sales and marketing, hired Pamela Cieplak, a consulting pharmacist with whom DiMaio had a longstanding business relationship, to conduct a 50-state survey of the laws regarding dosage

form substitution. Exhibit 28. Par intended to use the survey as a marketing tool to convince pharmacies and pharmacists to make the switch.

80. Par new that Cieplak had no legal training, but nevertheless did not have its inside or outside counsel review her work.

81. Cieplak reviewed and interpreted some of the state pharmacy statutes, but did not review state or federal Medicaid laws concerning drug costs and pricing.

82. On February 18, 2001, Cieplak sent DiMaio an email explaining that Texas and many other states prohibited pharmacists from choosing the dosage form without at least notifying the doctor:

> In many states, it looks like the states want pharmacists to notify the prescribing physician if they dispense a dosage form different from that prescribed (see Texas) . . . So it may be that, at least initially, pharmacists would have to notify prescribers that they were dispensing a tablet instead of a capsule in those states.

Exhibit 29. A draft of the state survey was also attached to Cieplak's email.

83. In her draft, Cieplak correctly cited the provision of Texas law dealing with dosage form substitution:

> The Texas Administrative Code, Chapter 309 states: "With the patient's consent and notification to the practitioner, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule . . ."

Exhibit 30 at 0923842. Cieplak's summary accurately reflects Texas law - if a patient consents and the pharmacist notifies the prescribing physician, the pharmacist can dispense a different dosage form.

84. In the final version of Cieplak's state survey, however, the quoted Texas law does not appear. Instead, Cieplak makes the following inaccurate statement about Texas law and its effect on fluoxetine substitution:

> The law is silent on the issue of generic substitution of different dosage forms. It is the professional responsibility of the pharmacist to determine the drug product to be selected.

Exhibit 28 at 0001489.

85. Cieplak similarly distorts and misquotes Michigan's generic substitution laws. The survey fails to mention explicit language which states that:

> [w]hen a pharmacist receives a prescription for a brand name drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product, the pharmacist shall *dispense a lower cost but not higher cost generically equivalent drug product* if available in the pharmacy. MCL 333.17755 (1); and,
>
> (4) A pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug product originally prescribed, unless agreed to by the purchaser.

86. In addition to deliberately misrepresenting state substitution laws, Par misrepresented FDA's position in order to convince pharmacies to participate in its fluoxetine switching scheme.

87. In a fluoxetine launch presentation created by Par for Caremark, dated June 11, 2001, Par stated:

> The FDA is stating that our 20 mg tablet is safe, effective, and has the same bioavailability and therapeutic effect as Prozac 20 mg *capsule*.

Exhibit 32 at 0006059 (emphasis in original).

88. Par's statement is wrong. The FDA's approval letter for Par's fluoxetine tablets compared *tablets with tablets* and made no mention of capsules:

> We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your fluoxetine hydrochloride tablets, 10 mg and

> 20 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Prozac Tablets, 10 mg and 20 mg of Eli Lily and Company).

Exhibit 33.

89. In addition to marketing the reimbursement differential on fluoxetine tablets, Par offered its customers significant financial incentives to induce participation in the illegal drug switching.

90. First, Par gave its customers free products or stocking rebates to ensure a certain minimum order quantity. For example, par gave Omnicare $100,000 as a stocking credit on fluoxetine tablets. Exhibits 34 and 35.

91. Second, Par created what it referred to as "Market Share Conversion Programs," which it offered to all of its major customers, including Walgreens and Omnicare. Par's objective was to increase the volume of fluoxetine tablets dispensed by inducing pharmacies to "convert" prescriptions for fluoxetine or Prozac capsules to fluoxetine tablets. The higher the percentage of fluoxetine tablets dispensed versus capsules, the greater the additional rebate that Par's customers would earn. For example, if Omnicare switched 80% of Prozac and fluoxetine prescriptions to tablets, they would be entitled to an "additional rebate" of 20% from Par. Exhibit 34.

92. Par put conditions on the cash payments, requiring customers to agree that they would "utilize Par's fluoxetine as the preferred product for all generic 10 mg, 20 mg, and 40 mg Prozac prescriptions." Exhibits 34 and 35. This meant that whenever a pharmacist received a prescription for fluoxetine or Prozac, Par's fluoxetine tablets would be dispensed regardless of the drug actually prescribed.

93. Par's payments to pharmacies to switch contributed to the success of its fluoxetine switching scheme. By March 2002, Omnicare had nearly achieved the 80% conversion rate Par required. As a result, on March 29, 2002, Omnicare received a 16% or $400,000 rebate from Par. Exhibit 36 at 0003968 and 0003971.

94. As a result of these marketing tactics, Walgreens and Omnicare agreed to buy fluoxetine tablets from Par for the purpose of engaging in the dosage form switching scheme.

95. In an email from Omnicare's Dan Maloney to Sam Enloe, Omnicare regional vice president, Maloney explained:

> As you all are aware, there is a[n] initiative to switch . . . fluoxetine 20 mg capsules to 20 mg tablets. I shared at the management meeting with each of you an [sic] financial analysis on the two drugs [fluoxetine and buspirone] and the opportunity to Omnicare. Both combined were worth well over half a million per month in profits.

Exhibit 22.

96. Walgreens also stressed the importance of the fluoxetine switching initiative. Tom Lawlor of Walgreens stated in an August 3, 2001 email to all pharmacy district managers:

> We need to focus on making an immediate conversion from Prozac (Lilly/Dista) to fluoxetine on every allowable prescription - refills and new. Please be sure all of your staff is aware of this and that they know the procedures to make these immediate conversions to the generic. Have a plan in place in your store for all of your staff, but especially for the in-window technicians, to make sure your store captures every opportunity the very first time one presents itself.

Exhibit 37.

97. Par's then CEO Scott Tarriff, wrote to Walgreens' management commending them for their participation in the fluoxetine program. Tarriff explained that, "Par elected to provide the fluoxetine opportunity to a very select group of customers. Walgreens was selected

for its progressive, forward thinking approach to pharmacy." Exhibit 38.

98. Tarriff's letter went on to state that:

> In fact, we believe that John Ziebell is perhaps the most creative and visionary purchasing executive in the industry. This is evidenced by Walgreen's participation in the ranitidine and fluoxetine programs. Par's decision to approach Walgreen with this opportunity was largely influenced by our belief that John had the vision to embrace this concept.

Exhibit 38.

99. By August 2001, Walgreens programmed its pharmaceutical distribution system so that all prescriptions for Prozac or generic fluoxetine would be filled with fluoxetine tablets. Walgreens made Par's fluoxetine tablets the only form of generic fluoxetine available to its retail customers.

100. If a prescription came in for capsules, Walgreens' pharmacy personnel could only fill it with Par's tablets. A similar switching system was implemented at Omnicare pharmacies.

101. Walgreens and Omnicare required their pharmacy staff to fill all Prozac and fluoxetine prescriptions with Par's tablets regardless of what the physician prescribed, in violation of state and federal law. Refills of Prozac and fluoxetine capsules previously filled with capsules were filled with tablets by both Walgreens and Omnicare without doctor or patient authorization for the switches.

102. In a September 21, 2001 email, George Riedl, Walgreens divisional manager for pharmacy purchasing boasted that:

> All generic [fluoxetine] SKU's combined produced $8.3 million in gross profit for August 2001 with store substitution reaching 85%. The 20 mg tablet alone produced $6.4 million in profit making it the #1 Rx profit item in the company.

Exhibit 37 at 04618.

103. Similarly, while summarizing some of the items discussed during an April 2002 regional managers meeting, Greg Primuth, a Walgreens district pharmacy supervisor stated: "Are you 90% on generic Prozac? Profit difference w/20 mg tablets is $64. This should be an automatic." Exhibit 39.

104. The conspiracy that Par created and implemented caused the submission and payment of numerous false claims to state and federal Medicaid programs.

105. As Par intended, Walgreens executives echoed the misrepresentation that Par's fluoxetine tablet was AB rated to Prozac or fluoxetine capsules in numerous emails to their pharmacy staff. In an August 3, 2001 email to all pharmacies, Tom Lawlor stated: "Fluoxetine tablets, capsules (10 & 20 mg strengths) 40 mg capsules . . . are all AB rated generic equivalents to Prozac (Lilly/Dista) . . . These very high profile, high volume AB rated generic equivalent represents a significant opportunity for all of us in several areas." Exhibit 37.

106. As with ranitidine, Par helped to cover the costs of Walgreens' "switch-back" from Par's fluoxetine tablets to capsules in response to the government investigation.

Buspirone Tablet Switch

107. Buspirone is the generic form of the anti-anxiety drug Buspar. Par switched the dosage *strength* of the drug rather than the form. Par devised and marketed a scheme to Omnicare and other pharmacies to evade Medicaid reimbursement limits for buspirone 15 mg tablets with a 7.5 mg tablet which had no price limit so that two Par tablets could be switched for the widely prescribed 15 mg dose.

108. Before Par entered the market, buspar was only available in strengths of 5 mg, 10 mg, and 15 mg. Generic buspirone became available in April 2001 when Buspar lost patent

protection. Prior to April 2001, all prescriptions for buspar tablets were filled with the three available dosages.

109. As with ranitidine and fluoxetine, Par marketed its 7.5 mg buspirone tablets as a means to increase profits by evading MACs, by filling prescriptions for Buspar and buspirone 15 mg tablets with two Par 7.5 mg tablets. Par began marketing the 7.5 mg tablets even though the federal price limits would not be implemented until at least six months after the 7.5 mg tablet became available. Before the launch, DiMaio sent an email to the Par sales force, explaining:

> Short term there is a significant financial advantage in dispensing 7.5 mg tablets, and long term we believe that reimbursement rates will be much more favorable on the 7.5 mg versus all the other strengths of buspirone.

Exhibit 41.

110. Par gave the same message to its pharmacy customers. Par's DiMaio sent a memo through Par Vice President Trendowicz to John Ziebell of Walgreens, stating that a "MAC will be set on buspirone 5, 10 and 15 mg when multiple manufacturers entered the market" and concluded that "since there will not be multiple manufacturers on the 7.5 mg, no HCFA MAC will be set for the 7.5 mg tablet." Exhibit 42.

111. Par repeated this message to other pharmacy customers, creating individualized financial analyses for pharmacies showing the incentives to be provided short term and the profits to be earned through MAC evasion over the long term.

112. In its launch presentation to Omnicare during the first 180 days before any Medicaid price limits could take effect, Par explained that it would provide a "conversion incentive rebate" to Omnicare worth more than $50,000. Given Par's aggressive pricing to induce switching, Omnicare would save significantly by using Par's 7.5 mg buspirone over using

Buspar 15 mg or Mylan's generic 15 mg tablet before Medicaid limits were implemented. Exhibit 43.

113. After Medicaid price limitations were implemented, Par used its standard financial analysis to show Omnicare how evading the MAC on buspirone 15 mg tablets created enormous profits, using a presentation virtually identical to the "Walgreens Ranitidine Analysis" used to sell ranitidine capsules. Exhibit 43.

114. Par's analysis showed that by dispensing two Par buspirone 7.5 mg tablets rather than one buspirone 15 mg tablet from another manufacturer, Omnicare could increase its annual yearly profit by $1 million.

115. Par promoted the opportunity for profit because the cost to the pharmacy for 60 of Par's 7.5 mg buspirone tablets was the same as the cost of 30 of another manufacturer's 15 mg buspirone tablets. The profits would not come from lower acquisition costs, but through higher Medicaid reimbursements.

116. Par's "HCFA MAC Per Prescription" chart illustrates the comparison. While there was a MAC of $12.83 per 30 buspirone 15 mg tablets, there was no such limit on Par's 7.5 mg tablets, resulting in a reimbursement of $46.30 for 60 of Par's 7.5 mg tablets. Julie Trendowicz, Par's Vice President of Sales and Marketing, testified that selling the favorable Medicaid reimbursement on Par's buspirone 7.5 mg tablets "was part of the promotional plan of the company." Exhibit 6 at Day 2, pp 481-482.

117. Par's customers used these marketing points with their own pharmacists. Dan Maloney of Omnicare stated in a December 2, 2001 email:

> Remember on average every buspirone switch is worth about 38 dollars and fluoxetine 18 dollars. Third when additional generic companies enter the market on fluoxetine early Feb. the prices will drop and Par will follow the price down on

> Bus 7.5 mg and fluox 20 mg tab. No one else will have these products so there will be minimal or no Mac's (sic). Hopefully profits will soar even more.

Exhibit 22.

118. In December 2002, at the end of the buspirone 15 mg tablet exclusivity period, a $0.44 federal upper limit was established. Exhibit 23. Similarly, states began to set maximum allowable costs for buspirone 15 mg tablets.

119. When these price limits came into effect, Omnicare and other Par customers who participated in the switching scheme reaped the financial benefit.

120. In Michigan during the month of March 2003, the Medicaid reimbursement for one buspirone 15 mg tablet was $0.28, while the reimbursement for two of Par's buspirone 7.5 mg tablets was more than six times as much at $1.70.

121. In addition to marketing the reimbursement differential between one 15 mg tablet and two of its 7.5 mg tablets, Par offered its customers significant incentives to induce switching.

122. Par's agreements with large pharmacy customers such as Omnicare and others had two key components. First, Par gave its customers free products or "conversion incentive rebates" to help the pharmacy start switching. For example, Par offered Omnicare $52,000 worth of buspirone 7.5 mg tablets as a "conversion incentive rebate" and an additional "customer rebate" worth $30,000. Exhibit 43 at 0004531.

123. Second, Par created a "market share conversion program" to pay all of its major customers, including Omnicare, for successfully switching buspirone 15 mg prescriptions to Par's 7.5 mg tablets. The more that those customers switched prescriptions to buspirone 7.5 mg tablets, the more Par would pay. Exhibit 44.

124. In an email from Omnicare's Maloney to Sam Enloe, an Omnicare regional vice president, Maloney explained:

> As you all are aware, there is a[n] initiative to switch buspirone 15 mg to 7.5 mg . . . I shared at the management meeting with each of you an [sic] financial analysis on the two drugs [fluoxetine and buspirone] and the opportunity to Omnicare. Both combined were worth well over half a million per month in profits.

Exhibit 22.

125. Omnicare required its pharmacy staff to fill all buspirone 15 mg prescriptions with Par's buspirone 7.5 mg tablet regardless of what the physician prescribed, in violation of state and federal law. Dan Maloney stated in a December 2001 email: "To date buspirone is not doing to[o] bad but that has been mainly because I have been hounding the pharmacies to do the switch." Exhibit 22.

Par Caused the Submission of False Claims

126. The conspiracy created and implemented by Par to switch drugs resulted in payment of numerous false claims by the Michigan Medicaid program.

127. When a Medicaid beneficiary submits a prescription to be filled, the pharmacy bills Medicaid or another third party payor. When a customer's prescription is paid in whole or in part by the state Medicaid program, the pharmacy collects any required co-pay and seeks reimbursement for the remainder of the cost from the state.

128. Federal law requires that Medicare and Medicaid items and services "will be provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1).

129. As a prerequisite or condition of payment and participation in government health programs under federal law, Walgreens, Omnicare, and other Medicaid providers must make the

following certifications on claims for reimbursement to state Medicaid programs:

> (1) This is to certify that the foregoing information is true, accurate, and complete.
>
> (2) I understand that payment of this claim will be from federal and state funds, and that any falsification, or concealment of a material fact, may be prosecuted under federal and state laws.

42 C.F.R. § 455.18.

130. As a condition of payment for services rendered to a Michigan Medicaid beneficiary, a provider must certify that a claim is true, accurate, prepared with the knowledge and consent of the provider, and does not contain untrue, misleading, or deceptive information. This certification is prima facie evidence that the provider knows that the claim is true, accurate, and does not contain misleading or deceptive information, and is filed in compliance with the policies, procedures, and instructions, and on forms established or developed pursuant to the Social Welfare Act. MCL 400.111b(17).

131. In order to submit Medicaid claims for reimbursement in Michigan, pharmacy providers must enroll in the State's Medicaid program by submitting provider applications and executing enrollment agreements. These agreements, and the Michigan Medicaid manual, require that enrolled providers certify compliance with state and federal laws, regulations, and all rules, regulations and policies of the Medicaid program. Providers attest to the truthfulness and accuracy of claims submitted, and acknowledge that they may be prosecuted, under civil or criminal laws, if their agent submits false claims or documents or if the pharmacy makes misrepresentations, conceals material facts, or conspires to engage in these actions. Exhibit 50.

132. Michigan Medicaid providers are required to comply with all the requirements established under MCL 400.111a(3) of the Social Welfare Act which requires that (a) claims

against the program are timely, substantiated, and not false, misleading, or deceptive; (b) that reimbursement is made for only medically appropriate services; (c) that reimbursement is made only for covered services (d) that reimbursement is not made to those providers whose services, supplies, or equipment cost the program in excess of the reasonable value received; and (e) that the state is a prudent buyer.

133. "Prudent buyer" is defined as a purchaser who does 1 or more of the following: (a) Buys from only those providers of services, supplies, or equipment to medically indigent individuals whose performance, in terms of quality, quantity, cost, setting, and location is appropriate to the specific needs of those individuals, and who, in the case of providers who receive payment on the basis of costs, comply with the prudent buyer concept of titles XVIII and XIX (of the Social Security Act, 42 U.S. C. A. § 1395 et seq. and 42 U.S.C.A. § 1396 *et seq.);* (b) Pays for only those services, supplies, or equipment that are needed or appropriate; and (c) Seeks to economize by minimizing cost. MCL 400.111a(4).

134. Michigan's statute and Medicaid Manual further state that a provider shall not charge the state more for a service rendered to a medically indigent individual than the provider's customary charge to the general public or another third party payer for the same or similar service. MCL 400.111b(12).

135. To the extent Par caused providers to supply Medicaid beneficiaries with illegally switched drug forms and strengths, and supplied Medicaid beneficiaries with drugs in the form and dosage not actually prescribed by the physician, such claims were not medically appropriate. Par caused false claims to be submitted to the Michigan Medicaid program.

136. Pursuant to Par's schemes, Walgreens, Omnicare, and other pharmacies submitted claims to the government certified as true, accurate, and complete, when in fact the drugs

charged to the government were not the drugs which had been prescribed for the Medicaid beneficiary. Instead, the drugs had been intentionally switched to another form or dosage in order to cause higher reimbursements by evading price limits set by Michigan's Medicaid program.

137. Pursuant to Par's schemes, Walgreens, Omnicare, and other pharmacies concealed material facts when they submitted claims to the Michigan Medicaid program. The drugs charged to Michigan's Medicaid program were not the drugs prescribed, but had been switched in form or strength and dispensed to cause Medicaid program to pay a higher price.

138. Pursuant to Par's schemes, Walgreens, Omnicare, and other pharmacies submitted claims to the State of Michigan pursuant to agreements that certified compliance with federal and state Medicaid laws, regulations, and other requirements. Par knew that its schemes caused these providers to violate laws and regulations prohibiting drug substitutions and evade state pricing regulations.

139. Walgreens, Omnicare, and other retail pharmacies typically batch and submit claims electronically through one or more state contractors responsible for processing prescription claims. The pharmacy is then paid by the State for approved claims.

140. On these electronic claims, the federally-mandated billing certification is made when the provider signs the remittance check or remittance advice.

> As an alternative to the statements required in § 455.18, the agency may print the following wording above the claimant's endorsement on the reverse of checks or warrants payable to each provider: "I understand in endorsing or depositing this check that payment will be from federal and state funds and that any falsification, or concealment of a material fact, may be prosecuted under federal and state laws.

42 C.F.R. § 455.19.

141. Because electronic claims are submitted and adjudicated instantaneously, Walgreens, Omnicare, and other pharmacies made representations and submitted claims to the State of Michigan on a daily basis.

142. State food and drug acts, pharmacy acts, and Medicaid laws prohibit filling a prescription with any drug other than the one prescribed. Par's conduct and conspiracy with Walgreens, Omnicare and other pharmacies cause pharmacies to regularly dispense Par drugs not prescribed by the Medicaid beneficiary's doctor. Par knowingly caused pharmacies to fill prescriptions with dosage forms or strengths other than the forms or strengths prescribed.

143. Under federal law, Walgreens, Omnicare, and other Medicaid providers must ensure that prescription drugs and other items "will be provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a). The illegal switching scheme was contrived to deliberately cause the Medicaid program to overpay.

Count I
Michigan Medicaid False Claim Act
MCL 400.607(1)

144. Plaintiff incorporates by reference paragraphs 1-141 of this complaint as if fully set forth.

145. Defendant knowingly caused to be presented false and fraudulent claims for payment to the Michigan Medicaid program in violation of MCL 400.607(1).

146. By virtue of the false or fraudulent claims made by the defendants, the State of Michigan suffered damages and therefore is entitled to the full amount received plus triple the amount of damages suffered by the state, pursuant to MCL 400.612, plus a civil penalty of $5,500 to $10,000 for each violation. MCL 400.612, as amended.

Count II
Michigan Medicaid False Claim Act
MCL 400.607(2)

147. Plaintiff incorporates by reference paragraphs 1- 144 of this complaint as if fully set forth.

148. Defendant caused claims it knew falsely represented that the goods for which the claims were made were medically necessary in accordance with professionally accepted standards. MCL 400.607(2).

149. By virtue of the false or fraudulent claims made by the defendants, the State of Michigan suffered damages and therefore is entitled to the full amount received plus triple the amount of damages suffered by the state, pursuant to MCL 400.612, plus a civil penalty of $5,500 to $10,000 for each violation. MCL 400.612, as amended.

Count III
Michigan Medicaid False Claim Act
MCL 400.606

150. Plaintiff incorporates by reference paragraphs 1-147 of this complaint as if fully set forth.

151. Defendant entered into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim under the social welfare act, in violation of MCL 400.606.

152. By virtue of the false or fraudulent claims made by the defendants, the State of Michigan suffered damages and therefore is entitled to the full amount received plus triple the amount of damages suffered by the state, pursuant to MCL 400.612, plus a civil penalty of $5,500 to $10,000 for each violation. MCL 400.612, as amended.

Count IV
Common Law Fraud

153. Plaintiff incorporates by reference paragraphs 1-150 of this complaint as if fully set forth.

154. Defendant caused to be made material and false representations with knowledge of their falsity or reckless disregard for their truth, with the intention that the State of Michigan act upon the misrepresentations to its detriment. The State of Michigan acted in justifiable reliance upon these misrepresentations and made payments.

155. As a result of these payments, the State of Michigan has been damaged in an amount to be determined at trial.

Count V
Unjust Enrichment

156. Plaintiff incorporates by reference paragraphs 1-153 of this complaint as if fully set forth.

157. Michigan Medicaid reimbursed for the subject drugs as prices greater than it would have been required to pay if defendant had not engaged in the unlawful conduct.

158. It would be inequitable for defendants to retain any of their ill-gotten gains earned as a result of the scheme alleged herein.

159. Michigan has been damaged and is entitled to the excess amounts paid because of defendant's unlawful scheme.

PRAYER FOR RELIEF

WHEREFORE, the State of Michigan requests that judgment be entered in its favor and against defendant as follows:

1. For Counts I, II, and III brought pursuant to the Michigan Medicaid False Claim

Act, the State seeks damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper. MCL 400.612.

2. For Counts IV and V, common law compensatory and punitive damages in an amount to be determined, together with costs and interest, and all such relief as may be just and proper.

Respectfully submitted,

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